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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,323	03/11/2004	Jessica G. Chiu	5618P3784	1769

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EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/800,323

Applicant(s)

CHIU ET AL.

Examiner

Laura C. Schell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 16-19, 26-39, 54-57 and 74-78, drawn to dilation catheter/system/kit/apparatus, classified in class 600, subclass 191.
- II. Claims 14-15, 40-53 and 58-73, drawn to an infusion catheter, classified in class 604, subclass 96.01.
- III. Claim 20, drawn to a method of making a catheter, classified in class 264, subclass 165.
- IV. Claims 21-25, drawn to a filtering device, classified in class 606, subclass 200.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the different inventions the apparatus in both groups I and II has a different design, in that in group I it is a dilation catheter, while in group II it is an infusion/dilation catheter, wherein the infusion part requires the catheter to have a different design, as evidenced by the claims. Furthermore, they have different effects,

as group I is used for dilation only, while group II is used for treatment after dilation, and therefore there is also a difference in operation between groups I and II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group I could be made a different process, such as by extrusion or by hand instead of by machine.

Inventions I and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the different inventions of group I and IV have different designs, in that group I is a dilation catheter, while group IV is an embolic filtering device. Therefore, groups I and IV also have different operations (one is for dilation, while four is for catching emboli) and different effects (one leaves a vessel dilated, while four removes emboli from the bloodstream). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of group I could be made a different process, such as by extrusion or by hand instead of by machine.

Inventions II and IV are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the inventions as claimed the different inventions of group II and IV have different designs, in that group II is an infusion/dilation catheter, while group IV is an embolic filtering device. Therefore, groups I and IV also have different operations (two is for infusion/dilation, while four is for catching emboli) and different effects (two treats a vessel medicinally and leaves a vessel dilated, while four removes emboli from the bloodstream). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IV and III are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case,

invention III is a process of making a balloon dilation catheter, while invention IV is an embolic filtering device.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

Species A: Figs. 3a, 3b, 4

Species B: Figs. 5, 6

Species C: Figs. 7, 8

Species D: Figs. 9, 10, 17

Species E: Fig. 11

Species F: Fig. 12
Species G: Fig. 13
Species H: Fig. 14
Species I: Fig. 15
Species J: Fig. 16
Species K: Fig. 18
Species L: Fig. 20
Species M: Fig. 21
Species N: Fig. 22
Species O: Figs. 23 and 24
Species P: Fig. 25
Species Q: Figs. 26-29
Species R: Fig. 30
Species S: Fig. 31
Species T: Fig. 32
Species U: Fig. 35
Species V: Fig. 36
Species W: Fig. 37
Species X: Fig. 38
Species Y: Fig. 39
Species Z: Fig. 40
Species AA: Figs. 41, 42a, 42b, 42c

Species BB: Fig. 43

Species CC: Fig. 44

Species DD: Fig. 45

Species EE: Fig. 46

Species FF: Fig. 47

Species GG: Fig. 48, 51

Species HH: Figs. 49a, 49b, 52

Species II: Figs 50, 53

Species JJ: Fig. 57

Species KK: Fig. 58

Species LL: Fig. 59

Species MM: Fig. 60

Species NN: Fig. 61

Species OO: Fig. 62

Species PP: Figs. 64a, 64b, 65a, 65b, 66a, 66b, 67a, 67b

Species QQ: Figs. 69a, 69b, 69c, 69d, 69e, 69f, 70

Species RR: Figs. 71a, 71b, 74a, 74b

Species SS: Figs. 72a, 72b

Species TT: Fig. 73

Species UU: Figs. 75a, 75b, 76, 77, 78, 79, 80

Species VV: Fig. 81

Species WW: Figs. 83-85

Species XX: Figs. 86, 87

Species YY: Fig. 88

Species ZZ: Fig. 89

The species are independent or distinct because each species discloses patentably distinct features of the catheter and catheter related inventions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.
MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LCS

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink that reads "Kevin C. Sirmons". The signature is written in a cursive, flowing style.